

Office of Environmental Health Hazard Assessment

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MEMORANDUM

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FROM: Robert A. Howd, Ph.D., Chief *RA, Howd*
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DATE: April 20, 2000

SUBJECT: PROPOSED ACTION LEVEL FOR NAPHTHALENE

Staff of the Office of Environmental Health Hazard Assessment (OEHHA) have reviewed your Department's proposed action level of 170 µg/L derived from the U.S. Environmental Protection Agency's (U.S. EPA) Integrated Risk Information System (IRIS), dated September 17, 1998. OEHHA concurs with this proposed action level for naphthalene.

Naphthalene is a bicyclic polyaromatic hydrocarbon that has been used extensively in ball (mothballs) or flake form as a larvacide, and as a repellent for various species. All pesticide uses of naphthalene were cancelled in California in 1991 due to data gap inadequacies, but several products remain registered with U.S. EPA for use in other states. The primary industrial use of naphthalene currently is in the manufacture of phthalic anhydride which is used extensively in the production of plasticizers. Naphthalene is a constituent of wood smoke and is found in coal tar; consequently, it can enter the environment from residential wood smoke and distillation of coal tar. Naphthalene degrades in the environment relatively quickly, and is not anticipated to bioaccumulate in terrestrial or aquatic systems.

Several human poisonings and deaths have occurred from the inhalation, dermal absorption, and ingestion of naphthalene. Moderate to high levels of naphthalene via all routes of exposure are known to cause hemolytic anemia in humans, especially in people who have

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glucose-6-phosphate dehydrogenase (G6PD) deficiency. Sensitive populations are infants, and people of African or Mediterranean descent, as they are more likely to have this enzyme deficiency. Ingestion of naphthalene also has resulted in cataracts and blindness.

Staff initially questioned whether the proposed action level was adequate for protecting public health from chronic, low-level exposures to naphthalene in drinking water. The reason is that U.S. EPA's value was in contradiction with the minimum risk level (MRL) derived by the U.S. Department of Health and Human Services' Agency for Toxic Substances and Disease Registry (ATSDR). Specifically, U.S. EPA identified the no-observable-adverse-effect-level (NOAEL) as 71 mg/kg-day, whereas ATSDR set the lowest-observable-adverse-effect-level (LOAEL) at 5.3 mg/kg-day. Each agency cited a different subchronic study to develop their respective conclusions.

After extensive review of the literature and discussions with key U.S. EPA staff, OEHHA believes that ATSDR's cited adverse effect of a statistically significant decrease in benzo(a)pyrene dehydrogenase activity is not considered biologically significant. Future reviews will consider any new information that may indicate otherwise, and the results anticipated from the National Toxicology Program (NTP) after its finalization of a naphthalene two-year inhalation study in June of this year. The preliminary pathology tables from the NTP study indicate that chronic exposure to naphthalene may cause cancer in experimental animals. There appears to be a statistically significant increase in nasal cavity neuroblastomas in both sexes.

OEHHA agrees with the U.S. EPA's use of the Battelle (1980) subchronic study for calculation of the action level. In this study, Fisher 344 rats were gavaged with naphthalene (>99 percent pure) in corn oil five days a week for 13 weeks. Groups of ten male and female rats were dosed at 0, 25, 50, 100, 200 or 400 mg/kg. These doses were adjusted to 0, 17.9, 35.7, 71.4, 142.9 and 285.7 mg/kg-day, respectively, for a seven days per week dose equivalent to derive the RfD. At the two highest doses, there were decreases in terminal body weight of greater than 10 percent, compared with controls. Specifically, females at the 400 mg/kg dose had a 23 percent decrease; males at the 400 and 200 mg/kg levels had a 29 percent and 12 percent decrease, respectively.

OEHHA has determined that U.S. EPA's selection of an NOAEL of 71 mg/kg-day based on decreased terminal body weight and their use of a total uncertainty factor of 3000 are appropriate for deriving an action level for naphthalene. The uncertainty factor accounts for extrapolation from rats to humans (10), protection of sensitive humans (10), extrapolation from subchronic to chronic exposure (10), and database deficiencies (3) including the lack of chronic oral and two-generation reproductive toxicity studies.

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Therefore, a public health protective concentration (C) for naphthalene of 170 µg/L in drinking water can be derived from the following equation:

$$C = \frac{\text{NOAEL} \times \text{BW} \times \text{RSC}}{\text{UF} \times \text{DWC}} = \frac{71 \text{ mg/kg-day} \times 70 \text{ kg} \times 0.2}{3000 \times 2 \text{ L/day}} = 0.17 \text{ mg/L} = 170 \text{ µg/L}$$

Where:

NOAEL = No-Observed-Adverse-EffectLevel,
BW = body weight (adult),
RSC = relative source contribution,
UF = uncertainty factor, and
DWC = drinking water consumption (adult).

Based on the health protective concentration calculated, OEHHA recommends and supports an action level of 170 ppb (ug/L) for naphthalene in drinking water. Should you have any questions about this review, please contact me at (510) 622-3168.

References

ATSDR (1995). Toxicological Profile for Naphthalene (Update). U.S. Department of Health and Human Services, Public Health Services, Agency for Toxic Substances and Disease Registry, Atlanta, Georgia.

Battelle Columbus Laboratories (1980). Unpublished subchronic toxicity study: Naphthalene (C52904), Fisher 344 rats. Prepared by Battelle Laboratories under NTP Subcontract 76-34-106002.

Bruce, Robert M., Ph.D. Personal Communication. U.S. Environmental Protection Agency, National Center for Environmental Assessment, Office of Research and Development. March and April 2000.

U.S. EPA (1998). Toxicological Review of Naphthalene (CAS No. 91-20-3). Support Document of the Summary Information on the Integrated Risk Information System (IRIS). Available on-line at <http://www.epa.gov.iris>.